



for posterior spinal surgery. The system includes a series of stainless steel sequential dilators and various sized reusable radiolucent oval cannulas and circular tubes. When used with the EBI® Array™ Spinal Fixation System, the use of the EBI® VuePASS™ Portal Access Surgical System is limited to the implant of a rod length of 50mm or less and excludes the use of system cross connectors or hooks.

- 5. Intended Use:** The EBI® Array™ Spinal Fixation System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, psuedoarthrosis, and failed previous fusion.

The EBI® VuePASS™ Portal Access System when used with the EBI® Array™ Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

- 6. Materials:** The components of the EBI® Array™ Spinal Fixation System are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and unalloyed titanium per ASTM F 67-00. The components of the EBI® VuePASS™ Portal Access System are manufactured from aluminum alloy as per ASTM B 221, titanium alloy as per ASTM F 136, stainless steel as per ASTM F 899, radel as per ASTM D 4181, and silicone.

**7. Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the proposed EBI<sup>®</sup> Array<sup>™</sup> Spinal Fixation System with the EBI<sup>®</sup> VuePASS<sup>™</sup> Portal Access Surgical System and the currently marketed EBI<sup>®</sup> Array<sup>™</sup> Spinal Fixation System. Verification testing demonstrated successful implantation of the EBI<sup>®</sup> Array<sup>™</sup> Spinal Fixation System utilizing the EBI<sup>®</sup> VuePASS<sup>™</sup> Portal Access Surgical System. It is substantially equivalent\* to the predicate device in regards to design, intended use, and materials.

\*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]



**4. Description of the device:** The EBI® SpineLink® - II Spinal Fixation System is a fixation device that utilizes interconnecting links, screws (fixed and polydirectional designs), transverse connectors, hooks, endcaps, locknuts, and link ties. The EBI® VuePASS™ Portal Access Surgical System is a retractor system for a minimally invasive approach for posterior spinal surgery. The system includes a series of stainless steel sequential dilators and various sized reusable radiolucent oval cannulas and circular tubes. When used with the EBI® SpineLink® II Spinal Fixation System, the use of the EBI® VuePASS™ Portal Access Surgical System is limited to the implant of link lengths of 36mm or less and excludes the use of system cross links.

**4. Intended Use:** The EBI® SpineLink® II Spinal Fixation System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, psuedoarthrosis, and failed previous fusion.

The EBI® VuePASS™ Portal Access System when used with the EBI® SpineLink® II Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

**6. Materials:** The components of the EBI® SpineLink® II Spinal Fixation System are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The components of the VuePASS™ Portal Access Surgical System are manufactured from aluminum alloy as per ASTM B 221, titanium alloy as per ASTM F 136, stainless steel as per ASTM F 899, radcl as per ASTM D 4181, and silicone.

## **7. Comparison of the technological characteristics of the device to predicate**

**devices:** There are no significant differences between the proposed EBI<sup>®</sup> SpineLink<sup>®</sup> II Spinal Fixation System with the EBI<sup>®</sup> VuePASS<sup>™</sup> Portal Access Surgical System and the currently marketed EBI<sup>®</sup> SpineLink<sup>®</sup> II Spinal Fixation System. Verification testing demonstrated successful implantation of the EBI<sup>®</sup> SpineLink<sup>®</sup> II Spinal Fixation System utilizing the EBI<sup>®</sup> VuePASS<sup>™</sup> Portal Access Surgical System. It is substantially equivalent\* to the predicate device in regards to design, intended use, and materials.

\*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 13 2004

Mr. Frederic Testa, RAC  
Regulatory Affairs Project Manager  
EBI, L.P.  
100 Interpace Parkway  
Parsippany, New Jersey 07054

Re: K042772

Trade/Device Name: EBI® Array Spinal Fixation System with VuePASS™ Portal Access Surgical System and EBI® SpineLink® Spinal Fixation System with VuePASS™ Portal Access Surgical System

Regulation Number: 21 CFR 888.3070, 21 CFR 888.3050

Regulation Name: Pedicle screw spinal system, Spinal interlaminar fixation orthosis,

Regulatory Class: III

Product Code: NKB, MNH, MNI, KWP, NBH

Dated: November 18, 2004

Received: November 19, 2004

Dear Mr. Testa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

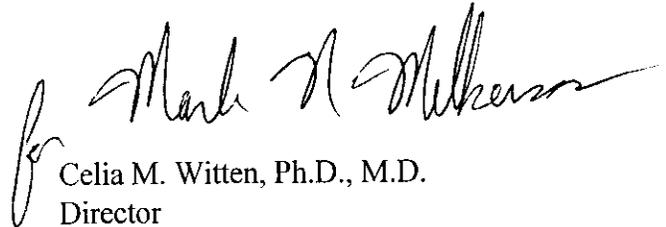
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-\_\_\_. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the printed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known):

Device Name:

EBI® Array Spinal Fixation System with VuePASS™ Portal Access Surgical System

Indications For Use:

The EBI® Array™ Spinal Fixation System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, psuedoarthrosis, and failed previous fusion.

The EBI® VuePASS™ Portal Access System when used with the EBI® Array™ Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

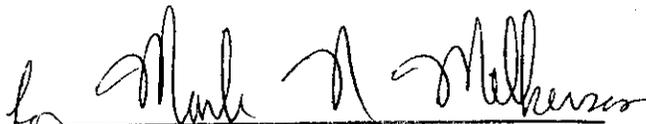
Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K042772

Statement of Indications for Use

Page 1 of 1

510(k) Number (if known):

Device Name:

EBI® SpineLink® II Spinal Fixation System with VuePASS™ Portal Access Surgical System

Indications For Use:

The EBI® SpineLink II Spinal Fixation System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, psuedoarthrosis, and failed previous fusion.

The EBI® VuePASS™ Portal Access System when used with the EBI® SpineLink® II Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use       
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark A. Melhous*  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K042772